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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,031	11/22/2000	Hannele Tolo	0365-0476P	4589

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	15

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,031	TOLO ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12,14*.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 October 2002 has been entered. Claims 1-19 are pending and under examination in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.

3. The rejection of claims 9 and 10 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in response to Applicant's amendment to these claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4, 11, 16, and 19 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by U.S. patent 6096872.

The '872 patent teaches addition of polysorbate 80 to immunoglobulins, followed by filtration through filters of less than 30 nm (column 4, lines 15-26), thus anticipating the limitations of claims 1-4, 11, and 16. That the filtrate contains the detergent is taught in column 6, lines 48-56. That the filter is not plugged, as claimed in instant claim 19, is an inherent property of the process and the addition of this limitation does not alter the method itself.

6. Claims 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by WO 96/11018, Yuen et al., 1996.

WO 96/11018 teaches the use of polysorbate 80 to stabilize interferons on p. 7, lines 13-31. Stabilization of purified alpha-interferon blends is taught on p. 8, lines 9-14. Such purified blends would inherently be free of virus; Applicant's methodology does not change the nature of the final, purified composition.

7. Claims 13-15 are also rejected under 35 U.S.C. 102(b) as anticipated by U.S. patent 5173415, Hiritani et al., 1992.

The '415 patent teaches pretreatment of viral removal filters with polysorbate 80 and subsequent filtration of interferon alpha in Example 4, columns 7 and 8. The resulting interferon would have the same characteristics as that claimed by Applicant, since the only difference in the method is that the '415 patent uses pretreatment of filters.

Claim Rejections - 35 USC § 103

8. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 6096872 in view of the Whatman Labsales Catalog, 1992.

The '872 patent teaches as set forth above but fails to teach prefiltration or sterile filtration. The Whatman Labsales catalog teaches filters for use in removing particulate matter on p. 21 and teaches sterile filters on p. 18. The Whatman catalog fails to teach a purification scheme requiring polysorbate and an anti-viral filter. However, it would have been obvious to one of ordinary skill in the art to combine the Whatman filters with the methods of the '872 patent to arrive at the claimed invention. One of ordinary skill would have been motivated to do so because the Whatman catalog teaches on p. 21 that clogged filters are a problem that can be resolved using the advertised prefilter, and because sterile filtration is an art-recognized necessity for the prevention of microbial and fungal growth in biological applications.

9. Claims 1-8 and 11-19 are rejected under 35 U.S.C. 103(a) as unpatentable over U.S. patent 5173415.

As stated above, the '415 patent teaches pretreatment of virus removal filters with polysorbate 80 and filtration of interferon alpha. The filters used are 25-50 nm (see abstract). The '415 patent further teaches in table 5 that this procedure results in yields that are superior to pretreatment with albumin. The '415 patent does not teach the combination of the polysorbate

80 with the interferon, as instantly claimed. However, it would be obvious to one of ordinary skill in the art to modify the methods of the '415 patent to arrive at the instant invention, because one of ordinary skill would have expected results similar to those obtained by pretreatment, and would further have known that detergents are commonly added to protein solutions as stabilizing agents. The '415 patent further fails to teach each of the subspecies of interferon alpha claimed by Applicant. However, it would be obvious to one of ordinary skill in the art to apply the teachings of the '415 patent to the purification of such subspecies. The '415 patent teaches that the method is successful for a variety of proteins (table 5) and thus one of ordinary skill would have expected it, and the obvious modification of co-addition of detergent, to be successful proteins closely related to those exemplified.

10. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as unpatentable over the '415 patent in view of the Whatman Labsales Catalog, 1992.

The '415 patent teaches as set forth above but fails to teach prefilters or sterile filtration. The Whatman Labsales catalog teaches filters for use in removing particulate matter on p. 21 and teaches sterile filters on p. 18. The Whatman catalog fails to teach a purification scheme requiring polysorbate and an anti-viral filter. However, it would have been obvious to one of ordinary skill in the art to combine the Whatman filters with the methods of the '415 patent to arrive at the claimed invention. One of ordinary skill would have been motivated to do so because the Whatman catalog teaches on p. 21 that clogged filters are a problem that can be resolved using the advertised prefilter, and because sterile filtration is an art-recognized necessity for the prevention of microbial and fungal growth in biological applications.

11. Claims 1-19 are rejected under 35 U.S.C. 103(a) as unpatentable over U.S. patent 4732683 in view of U.S. patent 4808315 for reasons of record in the office actions of paper nos. 5, 7, and 9.

Applicant has provided a declaration under 37 C.F.R. 1.132 indicating that the difference between the results obtained with albumin and with polysorbate 80 are statistically significant. Applicant states that the observed increase was unexpected and would be of importance for industrial processes. Applicant states that the detergent used in the '683 patent was Triton X-100, which must be removed from the composition, and that only Sendai virus was shown to be inactivated. Applicant states that the detergents disclosed in the '683 patent would not be useful for all viruses. Applicant further states that in the instant Application the detergents are not used for virus inactivation but to speed filtration. Applicant further argues that the '315 patent does not teach detergents.

Applicant's declaration and arguments have been fully considered but have not been found to be persuasive. It is agreed that the differences observed are statistically significant and of industrial importance. However, they are not unexpected in view of the prior art. The '415 patent teaches in table 5 that when virus removal filters were coated with Tween 80, which is polysorbate 80, a recovery rate of 91.4% was observed for alpha interferon, as compared to 53% for filters treated with albumin. Thus one familiar with the art would have expected better yields from processes using polysorbate 80 as compared to albumin; the '415 patent reports a 40% difference. Further, the '683 patent does teach that Tween 80/polysorbate 80 can be used for inactivating viruses, including but not limited to Sendai virus, in column 4, lines 1-15. It is not necessary that it be the preferred embodiment; it is taught as one of the alternatives. It is further

not necessary that the motivation for combining the use of detergent with virus removal filters; the resulting method is the same. Additionally, it is not necessary that each patent teach all the limitations of Applicant's claims. See *In re Keller*, 642 F.2d 413, 288 USPQ 871 9ccpa 1981:

> [it is not] necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
December 23, 2002